REMARKS

Claims 1-11, 13-16, and 28-31 are pending in the application. Allowable subject matter has been acknowledged in claims 4-11 and 13-16. The Examiner has rejected claims 1-3 and 28 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,279,582 to Davison et al. ("Davison"). The Examiner has additionally rejected claims 1-3 and 28-31 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,147,303 to Martin ("Martin").

Claims 1, 3, and 28 are currently amended. No new matter is being added by these amendments. Support for the amendments may be found at least in paragraphs 88-93.

Objections

The Examiner has indicated that claims 4-11 and 13-16 contain allowable subject matter but has objected to the claims as dependent on rejected claim 1. Applicant believes that claim 1 is allowable for at least the reasons discussed below and respectfully requests that the objection to claims 4-11 and 13-16 be withdrawn.

Claim Rejections Under 35 U.S.C. § 102

A rejection under 35 U.S.C. § 102 is proper only if each and every element of the rejected claim is disclosed in a single prior art reference. MPEP § 2131. The Examiner has rejected claims 1-3 and 28 under 35 U.S.C. § 102(b) as allegedly being anticipated by Davison and claims 1-3 and 28-31 under 35 U.S.C. § 102(b) as allegedly being anticipated by Martin.

Claim 1

Independent claim 1, which is currently amended, recites, "an actuator movably mounted to the housing and movable between a first unactuated position in which the needle is in the retracted position, an actuated position in which the needle is in the extended position, and a second unactuated position in which the needle is in the retracted position; and a retraction mechanism that automatically moves the actuator to the second unactuated position responsive to releasing the base from the site surface, wherein the actuator is not movable between the second unactuated position and the actuated position when the base is placed on a surface."

Davison discloses a device that covers the needle with a sleeve when the needle is withdrawn from the skin but does not disclose any mechanism by which the needle is prevented from moving repeatedly between the retracted position and extended position when the base is placed on a surface. Instead, the Davison device may be used for repeated injections; that is, Davison does not disclose, teach, or suggest any feature that, subsequent to release of the base from the surface, would prevent the needle from moving from the retracted position to the extended position if the base is again placed on a surface. More specifically, the Davison device has a needle that can move from the second unactuated position to the actuated position when the base is placed on a surface, which is directly contrary to the instant invention.

Martin discloses a device wherein the needle is secured in the extended position until manually released by the user. *See, e.g.*, col. 4, l. 67 to col. 5, l. 4 ("When syringe 10 is to be disposed of, the user need only depress plate 32 a little bit further allowing upper end 42 of spring 50, or flange 44, to engage an end of latch 54 so as to cam latch 54 aware from spring 40, enabling spring 40 to push against flange 44 to raise cylinder 16 out of sheath 12 as shown in FIG. 3."). During normal operation, regardless of whether or not the base is engaged with a

surface, the needle of the Martin device is in the extended position. *See, e.g.*, col. 4, ll. 8-12 ("Mounted in holes 50 and 52 of the sidewall of cup portion 18 is a spring biased latch 54, the purpose of which is to latch spring 40 and accordingly cylinder 16 in the downward position within sheath 12 prior to and during use of syringe 10, as shown in FIG. 2.").

Martin does not disclose, teach, or suggest "a retraction mechanism that automatically moves the actuator to the second unactuated position responsive to releasing the base from the site surface." Such a device would inherently conflict with the purpose of the Martin device, which is to provide a *manual* retraction mechanism. No retraction will occur in the Martin device without manual intervention, regardless of whether or not the base is on a site surface. Additionally, Martin is not responsive to release from the site surface because release of the base from the site surface does not activate retraction in the Martin device, only user operation can effectuate retraction. Even if a user were to manually activate the retraction mechanism of the Martin device while simultaneously releasing the base from the surface, such retraction would not be automatic or responsive to releasing the base from the site surface.

Neither Davison nor Martin discloses each and every limitation of claim 1 of the instant invention. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection.

Claims 2 and 3

Claims 2 and 3 depend from claim 1 and are allowable for at least the reasons discussed above. Claim 3 has been amended to recite that the retraction mechanism "permanently locks the needle in the retracted position after releasing the base from the site surface." As discussed above, Davison does not disclose any mechanism by which the needle is prevented from moving repeatedly between the retracted position and extended position when the base is placed on a

surface—i.e., the Davison device may be used for repeated injections. Likewise, Martin does not disclose or suggest any means by which the device is permanently locked in the retracted position. The Examiner's position is consistent with this amendment. As the Examiner stated the in Office Action with regard to Davison and Martin, "the retraction mechanisms will lock the needle in the retracted position even though the locking action will not be permanent." Neither Davison nor Martin discloses each and every limitation of claim 2 or 3 of the instant invention. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection.

Claim 28

Independent claim 28 recites that the retraction mechanism "automatically moves the needle from the extended position to the retracted position" and is "configured to begin moving the needle to the retracted position after release of the base from next to the surface." These features are not disclosed or suggested by Davison or Martin. As discussed above with regard to claim 1, Martin does not disclose automatic retraction of the needle, but rather relies on manual operation. The Davison device begins to move the needle to the retracted position simultaneously with withdrawal of the needle and before release of the base from next to the surface. That is, the base of the Davison will remain in contact with the area next to a surface of a needle-penetrating site until after the needle is entirely in the retracted position. Accordingly, neither Davison nor Martin disclose the retraction mechanism of claim 28, and not all elements of claim 28 are found in the references. For at least these reasons, Applicants respectfully request that the Examiner withdraw the rejections of claim 28.

Claims 29-31

Claims 29-31 depend from claim 28 and are allowable for at least the reasons discussed above, and Applicants respectfully request that the rejection be withdrawn.

Conclusion

In view of the current amendments and remarks, Applicants believe claims 1-11, 13-16, and 28-31 to be patentable and the application in condition for allowance, and such action is earnestly sought. Should the Examiner disagree, Applicants respectfully request that the Examiner contact the undersigned prior to the issuance of any official action.

Respectfully submitted,

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